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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,851	11/14/2005	Kunihiko Matsushita	KPO-TSC-P2/TK-91/US	2134
44702 7590 06/16/2009 OSTRAGER CHONG FLAHERTY & BROITMAN PC 570 LEXINGTON AVENUE FLOOR 17 NEW YORK, NY 10022-6894			EXAMINER MERCIER, MELISSA S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 06/16/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,851	Applicant(s) MATSUSHITA ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-30-06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Summary

Receipt of the Preliminary Amendment filed on November 14, 2005 is acknowledged. Claims 1-12 are pending in this application.

Priority

Applicant's claim of Priority to PCT/JP04/06451 filed on May 13, 2004 is acknowledged. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on July 30, 2006 is acknowledged. A signed copy is attached to this office action. It is noted that numerous united references were submitted with the application. If the references were not cited on submitted IDS, they have not been considered during the prosecution of the application. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (JP 11-001441) of record, in view of Blank et al. (US Patent 5,128,138).

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Hiraro discloses a percutaneous absorption patch comprising:

- a. 10-30% of a styrene-isoprene-styrene block copolymer;
- b. 10-60% of a softening agent;
- c. 20-60% of a tackyifying resin; and

d. 1-10% of hexylene glycol, all based on % weight. The medicinal ingredient is an estrogen, such as estradiol or progesterin such as norethisterone at a level of 0.1-10% weight (abstract). Rosin esters are disclosed for use as the tackifiers (paragraph 0016).

The patch is a laminated film (paragraph 0017).

Additives such as antioxidants, additional adhesives, water absorbing polymers, bulking agents, moisturizers and absorption enhancers can be added (paragraph 0019).

The use of polyvinylpyrrolidone is not disclosed. 17- β -estradiol is also not disclosed.

Blank discloses a mixture of estradiol or other estrogens and uncrosslinked, water insoluble vinylpyrrolidone copolymers (abstract). The amount of the polyvinylpyrrolidone is 0.1-90% by weight (column 5, lines 49-52).

Blank additionally discloses 17- β -estradiol is a suitable estradiol for topical delivery (column 5, lines 56-59).

It would have been obvious to one of ordinary skill in the art to have included the vinylpyrrolidone copolymer into the formulation of Hirano because Blank discloses the mixture provides a matrix which gradually releases the medicament upon application to the skin of a patient. It provides for a slow and sustained release of the medicament

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upon topical application to the skin so that the concentration of the drug in the blood plasma of the patient is maintained within the levels required for clinical efficacy (abstract).

Claims 4, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano et al. (JP 11-001441) of record, in view of Blank et al. (US Patent 5,128,138) and further in view of Azuma et al. (US Patent 5,200,190).

The combined teachings of Hirano and Blank are discussed above and applied in the same manner.

Hirano and Blank do not disclose the components of the laminated patch.

Azuma discloses percutaneous pharmaceutical preparations for the administration of estradiols (abstract). Laminated patches comprising backing layers of polyethylene terephthalate, and cellulose acetate, ethyl cellulose, vinyl acetate-vinyl chloride copolymers, nylon, ethylene-vinyl acetate copolymers, plasticized polyvinyl chloride, polyurethane, polyethylene, polyvinylidene chloride and aluminum, which Applicant has identified as suitable flexible polymer films in the specification on page 10.

The thickness of the layers were not disclosed, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared a film in varying thicknesses based on the needs of the patch. Applicants attention is directed to MPEP 2144.04 IV, which discloses changes in size and shape are not patentably distinct over a device which would perform the same function, in this

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cases both Azuma and Hirano are drawn to external patches for percutaneous delivery of estradiol.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit
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